UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,537	04/18/2001	Thomas L. Grey	212/323	9275

7590 06/04/2004

MICHAEL R. CRABB, ESQ.
ABBOTT LABORATORIES
DEPT. 0377 BLDG. AP6A-1, 100 ABOTT PARK ROAD
ABBOTT PARK, IL 60064

EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	13

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,537	GREY ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-5 and 8-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9-13 of prior U.S. Patent No. 6,282,443. This is a double patenting rejection.

Although the preamble of present claim 1 differs from the preamble of patented claim 9, the body of the claim 1 fails to give life, meaning and vitality to the preamble in accordance with MPEP 2112.02. The steps in the method for relieving menstrual cramps and dysmenorhea are identical to the steps for relieving nausea with the exception of a recitation of intended use (i.e., "...to relieve menstrual cramps or treat dysmenorhea"). It is therefore considered inherent that the patented method would relieve dizziness if such a condition were present during menstruation, and vice versa. A similar comment applies to claims 2 and 9 in view of patented claim 10, and present claim 8 in view of patented claim 9.

3. Claims 1-5 and 8-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 of prior U.S. Patent No. 6,658,298. This is a double patenting rejection.

Similar comments to those made above apply here as well.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 6-8, 13 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,282,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claim 6 is merely a broader version of patented claim 8 in that it does not recite a limitation covering the use of an electrode to apply an electric current. In essence, once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (*In re Goodman*, 11 F. 3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993)). A similar comment applies to claims 7, 13 and 14 in view of patented claim 8, and present claim 8 in view of patented claim 1.

6. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,393,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because in those cases where the application's claims are merely broader versions of the patented claims (e.g., claim 1's recitation of ventral wrist stimulation verses patented claim 6's recitation of the P6 point), the applicant is not entitled to a patent on the generic or broader invention as discussed above. Once again the preambles were considered, but deemed insufficient to saliently distinguish the claim sets in view of the resultant inherency factor.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertolucci (Pat. No. 4,981,146).

Bertolucci discloses a method that incorporates the steps of mounting a non-invasive nerve stimulation device onto the ventral side of the wrist (see for example Fig. 8), generating a stimulation signal (note col. 2, lines 23-29) and delivering it to the ventral side of the wrist (specifically the P6 meridian point). While the preambles of the present invention were considered, they were deemed to be insufficient in saliently distinguishing the method over the steps set forth by Bertolucci, which if performed, would inherently relieve any dizziness or vertigo present in the patient.

Regarding claims directed to the delivery of continuous stimulation, the examiner considers the device of Bertolucci to deliver continuous stimulation while the device is activated and producing pulses. Such stimulation would continue until the patient shut the unit off, or removed the wrist stimulator.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertolucci (Pat. No. 4,981,146).

Bertolucci does not explicitly discuss the use of intermittent stimulation such as disclosed on page 6, lines 4-6 of the present specification. Those of ordinary skill in the art, however, would have seen the obviousness of providing intermittent stimulation to account for the treatment of recurring bouts of nausea. Whether one would require continuous stimulation or intermittent stimulation would depend upon the needs of the particular patient and severity of condition being treated. Furthermore, the applicant gives no criticality as to the particular treatment regimen used, lending further support to the above assertion.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
May 27, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER